DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

PURGED

December 29, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 01 - 19

Gregory L. Ziegler
Owner and Operator
Ziegler Dairy Farm
5031 Church Road
Middleton, Wisconsin 53562

Dear Mr. Ziegler:

On August 17, 2000, investigators from the Food and Drug Administration (FDA) conducted an inspection at your dairy operation located in Middleton, WI. That inspection confirmed that you offered an animal for sale for slaughter as food in violation of Section 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act) and that you may have caused animal drugs to become adulterated within the meaning of Section 501(a)(5).

On or about April 18, 2000, you sold a cow, identified with back tag number 35HZ0956 (your cow #416), for slaughter as human food to ~~~~~~~~ USDA analysis of tissue samples collected from that animal identified the presence of 3.25-ppm gentamicin. No tolerance has been established for residues of gentamicin in the edible tissues of cows. The presence of this drug in edible tissue from this animal causes the food to be adulterated.

Our investigation also found that you hold animals under conditions that are so inadequate that diseased animals and/or animals bearing potentially harmful drug residues are likely to enter the food supply. You admitted to treating cow #416 with ~~~~ as an intra-mammary infusion for mastitis. As noted in form FDA-483 issued to you on August 17, 2000, you failed to maintain a record of drug use and animal withdrawal information to avoid unsafe residues. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in the labeling and for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit

depletion of potentially hazardous residues of drugs from edible tissues. Foods from animals held under such conditions are adulterated.

You are adulterating ~~~~ brand of gentamicin within the meaning of Section 501(a)(5) when you fail to use the drug in conformance with its approved labeling and fail to follow the directions in an extra-label prescription from a veterinarian.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for ensuring that your operations and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not occur. Failure to do so may result in regulatory action (such as seizure or injunction) without further notice to you.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be held responsible for a violation of the Act. The fact that you caused the adulteration of an animal with a drug that was shipped in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 working days of receipt of this letter of the steps you have taken to bring your dairy operation into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation that corrections have been made.

Your reply should be directed to Compliance Officer Timothy G. Philips at the address indicated on the letterhead.

Sincerely,

James A. Rahto
Director
Minneapolis District

TGP/ccl

xc: Leo Ziegler
Co-owner
Ziegler Dairy Farm
5031 Church Road
Middleton, WI 53562

xc w/cover letter:
[redacted], DVM
Owner and Operator
[redacted]